UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 8 1995

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: BPPD Review of Data Submitted by W.R. Grace and Company for the Registration of PFR-97, PFR-92 20% WDG, and PFR-MUP, each containing the active ingredient *Paecilomyces fumosoroseus var. Apopka*; and the Applicability of a Tolerance Exemption for this microbial. (Submission No.: S461171; DP. Barcode No: D216261; I.D. No.'s: 011688-RL PFR-MUP, 4F4372; Chemical ID No.: 115002, CAL EPA No.: 147708-NC).

TO: Shanaz Baccus, Regulatory Action Leader
Biological and Pollution Prevention Division (H7501W)

FROM: Cindy Schaffer, Microbiologist
Biological and Pollution Prevention Division (H7501W)

THROUGH: Roy Sjoblad, Ph.D., Team Leader
Biological and Pollution Prevention Division (H7501W)

ACTION REQUESTED:
BPPD has been asked to review the product analysis and toxicology data regarding PFR-97 (TGAI), PFR-97 20% WDG (EP) and PFR-MUP (EP), a microbial pesticide containing *Paecilomyces fumosoroseus var. Apopka* as the active ingredient used for the supression and control of whiteflies, aphids, thrips and spider mites on ornamentals and food crops in greenhouses and outdoors. BPPD has also been asked to comment on if the submitted data are adequate to support a tolerance exemption for this microbial pest control agent.

DISCUSSION/CONCLUSION:
CAL EPA has reviewed the toxicology data and the majority of the product chemistry for this product. BPPD has not only evaluated the results of the submitted data but will also consider the utilization of CAL EPA's reviews to streamline the Agencies review process. BPPD has performed a reassessment of each CAL EPA study review to ensure an accurate review assessment.

The registrant submitted a two-part CSF for all three products. The first part of each CSF has the concentration of each componenet before drying and the second part outlines the final

product. The second part of the CSF is noted above as this is the product submitted for registration.

One mutagenicity study was submitted and labelled as a cell culture study. Neither the mutagenicity nor the cell culture assays are required for registraton and the cell culture assays are only executed for viral pesticides and should not have been performed. The data support registration of all three products with the condition that W.R. Grace submit the methods for determining what kind and how many potential microbial contaminants are present in the manufacturing products and end-use products.

BPPD also accepts an exemption from tolerance based on a lack of pathogenicity of the active microbial component of this product.

DATA REVIEW RECORD

Product Name(s):PFR-MUP; PFR-97 ;PFR-97 20% WDG

Trade Name: *Paecilomyces fumosoroseus* Apopka, Strain 97

CAL REC.#:	MRID #:	SUBJECT:
52029-1, 2, 10, 13, 14, 16	432929-01	Product Chemistry (PFR-97 20% WDG)
N/A	431399-01	Product Chemistry (PFR-97 WDG)
N/A	431398-01	Product Chemistry (PFR-MUP)
131074	431639-01	Acute Oral Toxicity/Pathogenicity (152A-10)
131075	432255-01	Acute Dermal Toxicity (152A-11)
131083	431398-02	Acute Pulmonary Toxicity /Pathogenicity (152A-12)
131086	431398-03	Acute Intraperitoneal Toxicity /Pathogenicity (152A-13)
131096	431462-01	Primary Eye Irritation (152A-14)
131097	431462-02	Primary Dermal Irritation (152A-15)
	431462-03	Dermal Sensitization (152A-16)
134258	435348-02	Mutagenicity Testing (Ames Assay) (84-2)

SUMMARY OF DATA SUBMITTED:

Product Identification (PFR-97 20% WDG [EP]):

The following deficiency was noted: the methods for determining what kind and how many potential microbial contaminants are present in the manufacturing products and end-use products were not submitted.

CLASSIFICATION: SUPPLEMENTARY - May be upgraded to acceptable with the submission of the above data.

Product Identification (PFR-97 WDG [EP]):

The following deficiency was noted: the methods for determining what kind and how many potential microbial contaminants are present in the manufacturing products and end-use products were not submitted.

CLASSIFICATION: SUPPLEMENTARY - May be upgraded to acceptable with the submission of the above data.

Product Identification (PFR-MUP [TGAI]):

The following deficiency was noted: the methods for determining

what kind and how many potential microbial contaminants are present in the manufacturing products and end-use products were not submitted.
CLASSIFICATION: SUPPLEMENTARY - May be upgraded to acceptable with the submission of the above data.
NOTE: All toxicity studies were performed using TGAI only.
Acute Oral Toxicity/Pathogenicity (152A-10):
Paecilomyces fumosoroseus var. Apopka was not toxic, pathogenic or infectious when a 1.7×10^6 CFU dose was administered to rats orally.
CLASSIFICATION: ACCEPTABLE - TOX CATEGORY IV
Acute Dermal Toxicity (152A-11):
Overall, *Paecilomyces fumosoroseus* var. Apopka produced a mild irritation at 72 hours post dosing when a single 2 g/kg dose was administered dermally. Dermal irritation was completely reversed by day 7. The acute dermal LD_{50} was greater than 2 g/kg rat body weight.
CLASSIFICATION: ACCEPTABLE- TOX CATEGORY III (not required by U.S. EPA for registration)
Acute Intraperitoneal Toxicity/Pathogenicity (152A-12):
Paecilomyces fumosoroseus var. Apopka was not toxic, pathogenic or infective when a 1.6×10^7 CFU dose was administered to rats. Clearance was observed from the blood by day 2.
CLASSIFICATION: ACCEPTABLE - TOX CATEGORY IV
Acute Pulmonary Toxicity/Pathogenicity (151A-13):
Paecilomyces fumosoroseus var. Apopka was not toxic, pathogenic or infectious when a 10^8 conidia/animal dose was administered to rats. Complete clearance of the test microbe was demonstrated by day 8.
CLASSIFICATION: ACCEPTABLE - TOX CATEGORY IV
Primary Dermal Irritation (81-5):
No dermal irritation was present 72 hours after a 0.5 g dose was dermally applied to rabbits for a period of 4 hours.
CLASSIFICATION: ACCEPTABLE - TOX CATEGORY IV (not required by U.S. EPA for registration)
Primary Eye Irritation (152A-14):
Paecilomyces fumosoroseus var. Apopka produced a slight ocular irritation at 24 hours post dosing. Ocular irritation was no longer present by day 4.
CLASSIFICATION: ACCEPTABLE - TOX CATEGORY IV (not required by U.S. EPA for registration)
Dermal Sensitization (152A-15):
Paecilomyces fumosoroseus var. Apopka is not considered a dermal sensitizer.
CLASSIFICATION: SUPPLEMENTARY - Not required by U.S. EPA for registration
Mutagenicity Testing [Ames Assay] (84-2):
Paecilomyces fumosoroseus var. Apopka, Strain 97, did not cause an increase in the number of histidine revertants per plate in any tester strain either in the presence or absence of the microsomal enzyme, S9.
CLASSIFICATION: SUPPLEMENTARY - Not required by U.S. EPA for registration

DATA EVALUATION REPORT

Reviewed by: Cindy Schaffer, Microbiologist, BPPD CS
Secondary Reviewer: Roy Sjoblad, Ph.D., Team Leader, BPPD RS

STUDY TYPE:	Product Chemistry Data
MRID NO(S):	432929-01, 431399-01, 431398-01
TEST MATERIAL:	*Paecilomyces fumosoroseus* var. Apopka
SYNONYMS:	PFR-MUP; PFR-97; PFR-97 20% WDG
PROJECT NO's:	
SPONSOR:	W.R.Grace and Company, Columbia, MD
TESTING FACILITY:	
TITLE OF REPORTS:	
AUTHOR(S):	
STUDY COMPLETED:	
CONCLUSION:	The following deficiency was noted: the methods for determining what kind and how many potential microbial contaminants are present in the manufacturing products and end-use products were not submitted.
CLASSIFICATION:	SUPPLEMENTARY - All three submissions may be upgraded to acceptable with the submission of the above data.

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

Confidential Statement of Formula may be entitled to confidential treatment

Manufacturing process information may be entitled to confidential treatment

PRODUCT ANALYSIS

151A-10 Product Analysis and Disclosure of Ingredients

NOTE: California EPA has reviewed this information and it is attached to this document. The taxonomy of the microorganism was not discussed in the CAL EPA review. The taxonomy assessment is presented below. The only variations between the three products submitted for registration are the confidential statement of formula, part of each manufacturing process and the physical and chemical properties. The differences are listed below.

Taxonomy: See attached

[redacted]

Manufacturing process information may be entitled to confidential treatment

[redacted]

DISCUSSION: The following deficiency was noted: the methods for determining what kind and how many potential microbial contaminants are present in the manufacturing products and end-use products were not submitted.